Tranexamic acid
Hemostan®

250 mg Capsule
500 mg Capsule
100 mg/mL (250 mg/2.5 mL) Solution for Injection (IM/IV)
100 mg/mL (500 mg/5 mL) Solution for Injection (IM/IV)

Antifibrinolytic

FORMULATIONS

Each capsule contains:
Tranexamic acid..250 or 500 mg

Each mL of a 2.5 mL Solution for Injection contains:
Tranexamic acid..100 mg

Each mL of a 5 mL Solution for Injection contains:
Tranexamic acid..100 mg

PRODUCT DESCRIPTIONS

Tranexamic acid (manufactured by Amherst Laboratories, Philippines)

250 mg Capsule: Size #1 hard gelatin capsule with Ivory opaque cap and rich yellow opaque body

500 mg Capsule: Size #0 hard gelatin capsule with bright orange opaque cap and buff opaque body

Tranexamic acid (manufactured by Amherst Parenterals, Philippines)

100 mg/mL (250 mg/2.5 mL) Solution for Injection: Clear colorless, sterile, non-pyrogenic solution contained in a 3 mL clear ampule

100 mg/mL (500 mg/5 mL) Solution for Injection: Clear colorless, sterile, non-pyrogenic solution contained in a 5 mL clear ampule

CLINICAL PHARMACOLOGY

PHARMACODYNAMICS

Tranexamic acid is an anti-fibrinolytic agent. It is a competitive inhibitor of plasminogen activation and at much higher concentrations is a non competitive inhibitor of plasmin.

Human plasminogen contains lysine binding sites that are important for interactions not only with synthetic anti-fibrinolytic amino acid derivatives but also with α_2-antiplasmin and fibrin. One of these binding sites has a high affinity for tranexamic acid; the others have low affinity.

Tranexamic acid almost completely blocks the interaction of plasminogen and the heavy chain of plasmin with the lysine binding site of plasminogen. Saturation of this site with tranexamic acid prevents binding of plasminogen to the surface of fibrin. This process retards fibrinolysis because, although plasmin is still formed, it is unable to bind to fibrinogen or fibrin monomer. Conversely, when tranexamic acid blocks the binding site of plasmin, inactivation by α_2-antiplasmin is impossible.

In vitro, tranexamic acid 1 mg per mL does not aggregate platelets. Tranexamic acid in concentrations up to 10 mg per mL blood has no influence on platelet count, the coagulation time or various coagulation factors in whole blood or citrated blood from normal subjects. In contrast, tranexamic acid in concentrations of 10 mg and 1 mg per mL blood prolongs thrombin time.

PHARMACOKINETICS

Oral (Capsule) and Solution for Injection (IM/IV)

Tranexamic acid is rapidly absorbed from the gastrointestinal tract. Peak plasma levels after oral administration of 1 or 2 g are 8 or 15 mg/L, both obtained 3 hours after dosing. Bioavailability is about 30 to 50%. Food intake does not influence absorption.

After intramuscular (IM) administration of tranexamic acid at 500 mg dose, mean peak plasma concentration (12.36 ± 2.25 mcg/mL) is attained approximately after 1 hour. Following intravenous (IV) administration of tranexamic acid 10 mg/kg body weight, plasma concentrations at 1, 3 and 5 hours after injection are 18, 10 and 5 mg/L, respectively.

Tranexamic acid is widely distributed in the body and has very low protein binding, i.e., about 3% at therapeutic plasma levels and is accounted for by binding to plasminogen. It does not bind to serum albumin. The initial volume of distribution is about 9 to 12L. Tranexamic acid's antifibrinolytically active concentration (10 mcg/mL) remains in different tissues for about 17 hours and in the serum for up to 7 or 8 hours when administered 36 to 48 hours before surgery in four doses of 10 to 20 mg/kg body weight.

Tranexamic acid crosses the placenta. The concentration in cord blood after IV injection of 10 mg/kg to pregnant women is about 30 mg/L, as high as in the maternal blood. Tranexamic acid diffuses rapidly into joint fluid and the synovial membrane. In the joint fluid the same concentration is obtained as in the serum. The biological half-life of tranexamic acid in the joint fluid is about 3 hours. The concentration of tranexamic acid in a number of other tissues is lower than in blood. In breastmilk, the concentration is about one-hundredth of the serum peak concentration; in cerebrospinal fluid, it is about one-tenth that of plasma. The drug passes into the aqueous humor, the concentration being about one-tenth of the plasma concentration. Tranexamic acid has been detected in semen where it inhibits fibrinolytic activity but does not influence sperm migration.

Acetylation or deamination followed by oxidation or reduction are possible routes of biotransformation. After oral administration, approximately 50% of the parent compound, 2% of the deaminated dicarboxylic acid and 0.5% of the acetylated product are excreted.

Tranexamic acid's plasma half-life is approximately 2 hours. Urinary excretion is the main route of elimination via glomerular filtration.

After oral administration of a 10 to 15 mg/kg dose, the urinary excretion at 24 and 48 hours is 39 and 41%, respectively. The total amount of metabolites excreted in urine within 72 hours is less than 5%.

Overall renal clearance of IV tranexamic acid is equal to overall plasma clearance (110 to 116 mL/min) and more than 95% of the dose is excreted in the urine as the unchanged drug. Excretion of tranexamic acid is about 90% at 24 hours after IV administration of 10 mg/kg body weight.

Oral (Capsule)

Tranexamic acid is rapidly absorbed from the gastrointestinal tract. Peak plasma levels after oral administration of 1 or 2 g are 8 or 15 mg/L, both obtained 3 hours after dosing. Bioavailability is about 30 to 50%. Food intake does not influence absorption.

Tranexamic acid is widely distributed in the body and has very low protein binding, i.e., about 3% at therapeutic plasma levels and is accounted for by binding to plasminogen. It does not bind to serum albumin. Tranexamic acid's antifibrinolytically active concentration (10 mcg/mL) remains in different tissues for about 17 hours and in the serum for up to 7 or 8 hours when administered 36 to 48 hours before surgery in four doses of 10 to 20 mg/kg body weight.

Tranexamic acid crosses the placenta but secretion in breastmilk is low. No data are available concerning the concentration in gastric juice, but the clinical effect of tranexamic acid on gastrointestinal hemorrhage has been clearly demonstrated.

Acetylation or deamination followed by oxidation or reduction are possible routes of biotransformation. After oral administration, approximately 50% of the parent compound, 2% of the deaminated dicarboxylic acid and 0.5% of the acetylated product are excreted.

Tranexamic acid is excreted in the urine by glomerular filtration mainly as unchanged drug.The total amount of metabolites excreted in urine within 72 hours is less than 5%. After administration of a 10 to 15 mg/kg oral dose, the urinary excretion at 24 and 48 hours is 39 and 41%, respectively. Tranexamic acid's plasma half-life is approximately 2 hours.

INDICATIONS

For the treatment and control of excessive bleeding in various surgical and medical conditions including:

- ***Surgical***
  - General surgical cases
  - Cardiovascular surgery
    - Coronary artery bypass graft surgery (CABG) (especially in aspirin-treated patients)
    - Valvular heart surgery
    - Correction of congenital heart disease
    - Thoracic aortic surgery
  - Pulmonary surgery
  - Orthopedic surgery
    - Knee replacement or arthroplasty
    - Total hip replacement or arthroplasty
    - Scoliosis surgery
  - Traumatic injuries
  - Other operative procedures on the prostate, bladder, uterus, thyroid, ovaries, adrenals, kidneys, liver, brain, lymph nodes, and soft tissues
- ***Obstetric and Gynecologic***
  - Menorrhagia/Menometrorrhagia
  - Postpartum hemorrhage
  - Abortion
  - Conisation of the cervix
- ***Medical***
  - Epistaxis
  - Hemoptysis
  - Hematuria
  - Peptic ulcer disease with hemorrhage
  - Blood dyscrasias with hemorrhage (e.g., Hemophilia)
  - Hereditary angioneurotic edema
- ***Dental***
  - Following tooth extraction and dental surgery

DOSAGE AND ADMINISTRATION

Oral (Capsule) and Solution For Injection (IM/IV)

General Dosing Recommendations:
Dosing must be individualized and adjusted according to patient's age and response.

Intravenous (IV) Administration

- For IV infusion, tranexamic acid may be mixed with most solutions for infusion (e.g., electrolyte solutions, carbohydrate solutions, amino acid solutions, and Dextran solutions)
- The mixture should be prepared the same day the solution is to be used.
- Heparin may be added to tranexamic acid injection.
- Tranexamic acid injection should NOT be mixed with blood.
- Do not mix with solutions containing penicillin.
- Do not administer concomitantly with Factor IX Complex concentrates or Anti-inhibitor Coagulant concentrates, as risk of thrombosis may be increased.
- Administer parenteral format by slow IV injection to prevent dizziness and hypotension.
- **Do not inject more rapidly than 1 mL/minute.**

INDICATIONS			RECOMMENDED TRANEXAMIC ACID ADULT DOSE
SURGICAL	General Surgical Cases		**0.5 to 1 g (10 to 15 mg/kg body weight) IV every 8 to 12 hours** for the first few days immediately after surgery, **then, orally, 1 to 1.5 g every 6 to 8 hours**
	Cardio-vascular Surgery	Coronary Artery Bypass Surgery	Before surgery: **1 g IV bolus, or 30 mg/kg IV dose** in patients treated with aspirin During surgery: 200 mg/hour IV infusion
		Valvular Heart Surgery	**100 mg/kg body weight IV** before surgery
		Correction of Congenital Heart Disease in Children	Before surgery: Initial **IV bolus of 15 mg/kg body weight** After surgery: A second **IV bolus of 15 mg/kg body weight**
		Thoracic Aortic Surgery	**1 g IV** before skin incision, an IV infusion of 400 mg/hour during the operation, and 500 mg in the pump priming
SURGICAL	Orthopedic Surgery	Knee Replacement / Arthroplasty	Before surgery: **10 mg/kg body weight IV** After surgery: Another **10 mg/kg IV 3 hours later**
		Total Hip Replacement / Arthroplasty	Before surgery:**10 mg/kg initial IV bolus**, 2nd IV bolus of 10 mg/kg 3 hours later After surgery: Continuous IV infusion of 1 mg/kg per hour for 10 hours
		Scoliosis Surgery	Initial dose of **10 mg/kg body weight IV** and IV infusion of 1 mg/kg per hour
	Prostatectomy		**0.5 to 1 g IV every 8 hours (the first injection given during the operation) for the first three days after surgery, then orally, 1 to 1.5g every 6 to 8 hours until macroscopic hematuria is no longer present**
OBSTETRIC AND GYNECOLOGIC		Menorrhagia / Metrorrhagia	**Orally, 1 to 1.5 g every 6 to 8 hours** for 3 to 4 days
		Postpartum hemorrhage	**1 g IV (taking 1 minute to administer)**; if bleeding continues,repeat 1 g after 30 minutes,then orally,1 to1.5 g(25 mg/kg body weight) every 6 to 8 hours
MEDICAL		Conisation of the Cervix	After surgery: **Orally, 1.5 g every 8 hours** for 12 to 14 days
		Epistaxis	**Orally, 1.5 g every 8 hours** for 4 to 10 days
		Gastro intestinal hemorrhage	**1 g IV every 4 hours** for a maximum of 3 days, then **orally, 1.5 g every 6 hours** for a maximum of 4 days
		Hematuria	**Orally, 1 to 1.5 g every 8 to 12 hours** until macroscopic hematuria is no longer present
		Hereditary angioneurotic edema	**Orally, 1 to 1.5 g every 8 to 12 hours** as intermittent or continuous treatment depending on the prodromal symptoms of the patient.
DENTAL		Dental surgery in patients with coagulopathies	Immediately before surgery: **10 mg/kg body weight IV** After surgery: **Orally, 1 to 1.5 g(25mg/kg body weight) every 6 to 8 hours** for 6 to 8 days
Or, as prescribed by a physician			

Dosage in children:

Tranexamic Acid Dosage	
IV	Oral
10 mg/kg body weight per dose, two or three times a day, depending on the indication	**25 mg/kg body weight per dose**, two or three times a day, depending on the indication

Dosage in renal insufficiency:

Serum Creatinine (mg/dL)	Tranexamic Acid Dosage	
	IV	Oral
1.36 to 2.83	10 mg/kg body weight twice a day	15 mg/kg body weight twice a day
2.83 to 5.66	10 mg/kg body weight once a day	15 mg/kg body weight once a day
> 5.66	10 mg/kg body weight every 48 hours or 5 mg/kg body weight every 24 hours	15 mg/kg body weight every 48 hours or 7.5 mg/kg body weight every 24 hours

Oral Capsule

INDICATIONS		RECOMMENDED TRANEXAMIC ACID ADULT DOSE
SURGICAL	General Surgical Cases	0.5 to 1 g (10 to 15 mg/kg body weight) IV every 8 to 12 hours for the first few days immediately after surgery, then, **orally, 1 to 1.5 g every 6 to 8 hours**
SURGICAL	Prostatectomy	0.5 to 1 g IV every 8 hours (the first injection given during the operation) for the first three days after surgery, then **orally, 1 to 1.5 g every 6 to 8 hours until macroscopic hematuria is no longer present**
OBSTETRIC & GYNECOLOGIC	Menorrhagia / Metrorrhagia	**Orally, 1 to 1.5 g every 6 to 8 hours** for 3 to 4 days
	Postpartum hemorrhage	1 g IV (taking 1 minute to administer); if bleeding continues, repeat 1 g after 30 minutes, then **orally, 1 to1.5 g (25 mg/kg body weight) every 6 to 8 hours**
	Conisation of the Cervix	After surgery: **Orally, 1.5 g every 8 hours** for 12 to 14 days
MEDICAL	Epistaxis	**Orally, 1.5 g every 8 hours** for 4 to10 days.
	Gastrointestinal hemorrhage	1 g IV every 4 hours for a maximum of 3 days, then **orally, 1.5 g every 6 hours** for a maximum of 4 days
	Hematuria	**Orally, 1 to 1.5 g every 8 to 12 hours** until macroscopic hematuria is no longer present
	Hereditary angioneurotic edema	**Orally, 1 to 1.5 g every 8 to 12 hours** as intermittent or continuous treatment depending on the prodromal symptoms of the patient
DENTAL	Dental surgery in patients with coagulopathies	Immediately before surgery: 10 mg/kg body weight IV After surgery: **Orally, 1 to 1.5 g (25 mg/kg body weight)every 6 to 8 hours** for 6 to 8 days.
Or, as prescribed by a physician		

Dosage in children:
25 mg/kg body weight per dose, two or three times a day, depending on the indication

Dosage in renal insufficiency:

Serum Creatinine (mg/dL)	Tranexamic Acid Dosage
1.36 to 2.83	15 mg/kg body weight twice a day
2.83 to 5.66	15 mg/kg body weight once a day
> 5.66	15 mg/kg body weight every 48 hours or 7.5 mg/kg body weight every 24 hours

CONTRAINDICATIONS

- Hypersensitivity to tranexamic acid or any component of the product
- Active thromboembolic disease (e.g., deep vein thrombosis, pulmonary embolism, cerebral thrombosis)
- History of thrombosis or thromboembolism (e.g., retinal vein or artery occlusion) or intrinsic risk of thrombosis or thromboembolism (e.g., thrombogenic valvular disease, thrombogenic cardiac rhythm disease, hypercoagulopathy), unless at the same time it is possible to give treatments with anticoagulants
- Patients receiving thrombin because of increased risk of thrombosis
- Patients with acquired disturbances of color vision. If disturbances of color vision arise during the course of treatment, discontinue the drug
- Patients with subarachnoid hemorrhage since cerebral edema and cerebral infarction may be caused by tranexamic acid in such cases

WARNINGS AND PRECAUTIONS

Thromboembolic Events

Venous and arterial thrombosis or thromboembolism, central retinal artery and vein obstruction, and intracranial thrombosis have been reported in patients treated with tranexamic acid. Patients with a high risk for thrombosis (a previous thromboembolic event and a family history of thromboembolic disease) should use tranexamic acid only if there is a strong medical indication and under strict medical supervision.

***Use with Hormonal Contraceptives**:* Combination hormonal contraceptives are known to increase the risk of venous thromboembolism, as well as arterial thromboses such as stroke and myocardial infarction. Since tranexamic acid is antifibrinolytic, the concomitant use of hormonal contraception and tranexamic acid may further exacerbate this increased thrombotic risk. There are no data on the risk of thrombotic events with the concomitant use of tranexamic acid with hormonal contraceptives. Thus, women using hormonal contraception should use tranexamic acid only if there is a strong medical need and the benefit of treatment will outweigh the potential increased risk of a thrombotic event.

***Use with Factor IX Complex Concentrates or Anti-inhibitor Coagulant Concentrates**:* Tranexamic acid is not recommended in patients taking either Factor IX complex concentrates or anti-inhibitor coagulant concentrates because of increased risk of thrombosis.

***Use with All-trans Retinoic Acid (Oral tretinoin)**:* Exercise caution when prescribing tranexamic acid to women with acute promyelocytic leukemia taking all-trans retinoic acid for remission induction because of possible exacerbation of the procoagulant effect of all-trans retinoic acid.

Renal Insufficiency

Reduce dose in patients with renal insufficiency because of the risk of drug accumulation.
Urinary tract obstruction due to clot formations in patients with severe bleeding from the upper urinary tract has been reported in patients taking tranexamic acid.

Treatment with tranexamic acid is not indicated in hematuria caused by diseases of the renal parenchyma. Intravascular precipitation of fibrin frequently occurs and may aggravate the disease. Furthermore, antifibrinolytic treatment carries the risk of clot retention in the renal pelvis in cases of massive renal hemorrhage of any cause.

Disseminated Intravascular Coagulation

Patients with disseminated intravascular coagulation who require treatment with tranexamic acid must be under the strict supervision of a physician experienced in treating this disorder.

Extravascular Clots

Indissoluble clots may develop in body cavities such as pleural space and joint spaces due to extravascular clots which may be resistant to physiological fibrinolysis.

Subarachnoid Hemorrhage

Cerebral edema and cerebral infarction may be caused by tranexamic acid use in women with subarachnoid hemorrhage.

Convulsion

Convulsions have been reported in association with tranexamic acid treatment. Patients should be carefully monitored, and appropriate measures, such as discontinuing treatment, should be taken if any abnormality is observed.

Severe Allergic Reactions

A case of severe allergic to tranexamic acid was reported in a clinical trial, involving a subject who experienced dyspnea, tightening of throat, and facial flushing that required emergency medical treatment. A case of anaphylactic shock has also been reported involving a patient who received an intravenous bolus of tranexamic acid.

Visual Abnormalities

For patients on prolonged treatment with tranexamic acid, perform an ophthalmological examination (including visual acuity, color vision, eyeground, and visual fields) before and at regular intervals during treatment, since visual abnormalities are the most frequently reported adverse reactions in some postmarketing studies. Discontinue tranexamic acid if changes are found.

In clinical trials, no retinal changes have been reported in patients treated with tranexamic acid for weeks and months. However, focal areas of retinal degeneration have developed in cats, dogs, rabbits, and rats following oral or IV tranexamic acid at doses between 126 and 1,600 mg/kg/day (3 to 40 times the recommended human dose) from 6 days to 1 year.

Irregular Menstrual Bleeding

Patients with irregular menstrual bleeding should not use tranexamic acid until the cause of irregular bleeding has been established. Consider an alternative treatment if menstrual bleeding is not adequately reduced by tranexamic acid.

Effect on Ability to Drive and Use Machines

Tranexamic acid may cause dizziness and therefore may influence the ability to drive or use machines. Exercise caution when driving vehicles or operating machinery.

INTERACTIONS WITH OTHER MEDICAMENTS

Thrombin: Concomitant use is contraindicated due to increased risk of thrombosis
Batroxobin: May cause thromboembolism
Coagulation Factor Agents (e.g.,Eptacog-alfa): Coagulation may be further activated at sites with enhanced local fibrinolysis such as the oral cavity
Hemocoagulase: Coadministration at high doses may cause thrombosis
Hormonal Contraceptives: May increase the risk of thrombosis
Clotting Factor Complexes (e.g.,Factor IX complex concentrates or anti-inhibitor coagulant concentrates): May increase the risk of thrombosis
All-trans Retinoic Acid (Oral tretinoin): May increase the procoagulant effects of all-trans retinoic acid
Tissue Plasminogen Activators: Concomitant therapy may decrease the efficacy of both tranexamic acid and tissue plasminogen activators
Others:

- Simultaneous treatment with anticoagulants should be under the strict supervision of an expert physician
- Tranexamic acid may counteract the thrombolytic effect of fibrinolytic preparations

STATEMENT ON USAGE FOR HIGH RISK GROUPS

Pregnancy: Pregnancy Category B. There are no adequate and well controlled studies in pregnant women. However, tranexamic acid crosses the placenta and appears in cord blood. Use in pregnancy only if clearly needed.

Lactation: Tranexamic acid is present in breast milk at 1% of the corresponding serum levels. Use in lactation only if clearly needed.

Elderly: Since elderly patients often have reduced physiological function, careful supervision and dosage reduction are recommended.

Children: Tranexamic acid has had limited use in children, principally in tooth extraction.

UNDESIRABLE EFFECTS

The most frequently reported adverse effects with tranexamic acid include gastrointestinal disturbances (nausea, vomiting, and diarrhea). These adverse effects may disappear when the dose is reduced.

Blood and lymphatic system disorders**:** Anemia
Immune system disorders**:** Hypersensitivity reactions including anaphylaxis, anaphylactic shock, anaphylactoid reactions
Nervous system disorders**:** Cerebral thrombosis, convulsion, dizziness, drowsiness, giddiness, headache, left hemiparesis, left-sided weakness, migraine, neurologic dysfunction, neurological complications, stroke
Eye disorders**:** Chromatopsia, ligneous conjunctivitis, retinal/artery occlusion, visual disturbances including impaired color vision, visual impairment
Cardiac disorders**:** Arrhythmia, atrial fibrillation, cardiac ischemia, cardiac problems, cardiogenic shock, chest pain, heartblock, myocardial infarction, ventricular arrhythmia, ventricular tachycardia
Vascular disorders**:** Thromboembolic events (e.g., deep vein thrombosis, pulmonary embolism, cerebral thrombosis, acute renal cortical necrosis, central retinal artery and vein obstruction), arterial or venous thrombosis, hypotension, shock
Respiratory, thoracic and mediastinal disorders**:** Dyspnea, nasal and sinus symptoms including respiratory tract and sinus congestion, pulmonary complications, pulmonaryedema, respiratory failure, sinusitis, acute sinusitis, sinus headache, allergic sinusitis, sinus pain, multiple allergies, seasonal allergies
Gastrointestinal disorders**:** Abdominal pain, abdominal tenderness and discomfort, anorexia, bowel infarction, gastrointestinal discomfort, heartburn
Skin and subcutaneous tissue disorders**:** Allergic skin reactions, dermatitis allergic, itching, rash
Musculoskeletal and connective tissue disorders**:** Arthralgia, back pain, muscle cramps and spasms, musculoskeletal discomfort, musculoskeletal pain, myalgia
Renal and urinary disorders**:** Renal dysfunction, renal failure, renal insufficiency
General disorders and administration site conditions**:** Fatigue, malaise

OVERDOSE AND TREATMENT

There are limited data on tranexamic acid overdosage. Symptoms may include dizziness, headache, nausea, vomiting, diarrhea, orthostatic symptoms, hypotension, and convulsions.

There is no known antidote for tranexamic acid overdose. In cases of overdose, discontinue treatment and institute symptomatic and supportive measures as required. Activated charcoal may decrease absorption if given within 1 or 2 hours after ingestion.

Administer activated charcoal via a nasogastric tube once the airway is protected in patients who are not fully conscious or have impaired gag reflex.

Monitor vital signs to detect a hypotensive episode. In patients with severe vomiting or diarrhea, monitor fluid and electrolyte levels and administer intravenous fluids and replace electrolytes as necessary. Monitor urine output and maintain adequate diuresis. Monitor for clinical evidence of thromboembolic complications (e.g., chest pain, shortness of breath, flank pain, extremity pain). Because there is a risk of thrombosis in predisposed individuals, anticoagulant therapy should be considered in these patients.

In symptomatic patients, support cardiac and respiratory function. Monitor blood count, renal function, pulse oximetry and/or blood gases and obtain a chest x-ray. Obtain an ECG and institute continuous cardiac monitoring.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

STORAGE CONDITION

Store at temperatures not exceeding 30°C.
Keep the product out of sight and reach of children.
Protect from light.

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription

AVAILABILITY

*Tranexamic acid (Hemostan®) 250 mg capsules, box of 100 capsules
*Tranexamic acid (Hemostan®) 500 mg capsules, box of 100 capsules
**Tranexamic acid (Hemostan®) 250 mg/2.5 mL Solution for Injection, box of 5 ampules
**Tranexamic acid (Hemostan®) 500 mg/5 mL Solution for Injection, box of 5 ampules

*Manufactured by AMHERST LABORATORIES, INC.
UNILAB Pharma Campus, Barangay Mamplasan
Biñan, Laguna, Philippines
For UNILAB, Inc.
No. 66 United Street, Mandaluyong City
Metro Manila, Philippines

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No. 66 United Street, Mandaluyong City
Metro Manila, Philippines

Date of First Authorization:
DR-5167 - Hemostan 250 mg Capsule: 1 August 2007
DRP-2847 - Hemostan 500 mg Capsule: 25 January 2013
DR-4759 - Hemostan 250 mg/2.5 mL Ampule : 21 July 1999
DR-XY229 - Hemostan 500 mg/5 mL Ampule : 30 September 1999

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